



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

Re: Stelara

Patent Nos. 6,902,734 and 7,166,285

Docket Nos. FDA-2010-E-0036

FDA-2010-E-0032

MAR 24 2010

The Honorable David J. Kappos  
Under Secretary of Commerce for Intellectual Property  
Director of the United States Patent and Trademark Office  
Mail Stop Hatch-Waxman PTE  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 6,902,734 and 7,166,285 filed by Centocor Ortho Biotech Inc., under 35 U.S.C. § 156. The human biological product claimed by the patents is Stelara (ustekinumab), which was assigned biologics license application (BLA) No. 125261/0.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1).

The BLA was approved on September 25, 2009, which makes the submission of the patent term extension applications on November 20, 2009, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patents are eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

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cc: Philip Johnson, Esq.  
Johnson & Johnson  
Attn: Eric A. Dichter  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933